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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/669,353	09/26/2000	David W. Pennington	1417Q P 279	4575

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EXAMINER

LAM, ANN Y

ART UNIT	PAPER NUMBER
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1641

DATE MAILED: 08/26/2003

11

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/669,353

Applicant(s)

PENNINGTON ET AL.

Examiner

Ann Y. Lam

Art Unit

1641

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 04 June 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-37 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-37 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-11 and 14-37 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 recites the limitation "the medical tubing" in line 5. There is insufficient antecedent basis for this limitation in the claim.

Claims 5, 8 and 15 recites "two first feed conduits", in line 17. It is unclear whether or not this is in addition to the first feed conduit in line 14, i.e., it is unclear whether or not claim 5 claims at least two first feed conduits or at least three first feed conduits. Similarly, claim 5 recites "two second feed conduits", in line 18. It is unclear whether or not this is in addition to the second feed conduit in line 15.

Likewise, claim 6 recites "three first feed conduits" in line 17, and "three second feed conduits" in line 18; and claim 7 recites "four first feed conduits" in line 17, and "four second feed conduits" in line 18. It is unclear whether or not these feed conduits are in addition to the "first feed conduits" in line 14 and "second feed conduits" in line 15 of the respective claims.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

1. Claims 1-4, 9-14, 16 and 18-37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Duronio et al., 6,328,229.

Duronio et al. discloses the invention substantially as claimed. More specifically, Duronio et al. discloses a tubular component (distal end of 16); a spray tip assembly (12) attached to the tubing, the spray tip assembly comprising: a first mechanical breakup unit (26) having at least one feed port (see proximal end of 26) configured to direct a fluid into a first spin chamber and issue into a first exit port (55a), and a second mechanical breakup unit (28) positioned alongside the first mechanical breakup unit and having at least one feed port (see proximal end of 28) configured to direct a fluid into a second spin chamber and issue into a second exit port (55b), wherein the first and second exit ports extend through the external surface of the spray tip, see figures 5 and 6.

As to claim 2, a first funneling portion (see 26 in Figure 5) adjacent the first spin chamber and having a sloped sidewall configured to direct the fluid issuing into the first exit port; and a second funneling portion as claimed are disclosed.

As to claim 3, the device is dimensioned to produce a spray from the exit ports and a force of a single magnitude is used to propel fluid as claimed, see column 4, line 58 – column 5, line 9.

As to claim 4, a first fluid source (16) in fluid communication via the tubular component with at least one first feed conduit and a second fluid source (18) as claimed, wherein the at least two conduits deliver fluid to different mechanical breakup units are disclosed.

As to claims 5-8, 12, 13 and 15, the spin chambers are located at (50 and 52), see Figure 5.

As to claims 9 and 10, the fluids are fibrinogen and thrombin, see column 1, lines 18-19.

As to claims 12 and 13, the device is capable of having a resulting spray cone of one of the fluids having a width greater than a resulting spray cone of the other fluid. (The spray cone of the fluids have different widths depending on the viscosity of the fluid and the velocity of the fluid being ejected.)

As to claim 14, feed ports (see proximal ends of 26 and 28) directing fluid from the feed conduits to the spin chamber of each mechanical breakup unit are disclosed.

As to claim 16, at least one additional conduit (see distal end of 26) is positioned through the spray unit assembly.

However Duronio et al. does not disclose that the spray tip assembly has a diameter of at most about 12 mm. Also, as to claims 18-37, Duronio et al. does not disclose specifically the rate at which the fluid exits the device, nor the diameter of the

Art Unit: 1641

spin chambers, nor the angle of the sloped sidewall, nor the width of the feed ports, nor the height of the feed ports, nor the diameter of the exit port, nor the length of the exit port, nor the length of the exit port, nor the ratio of the diameter of the spin chamber to the diameter of the exit port, nor the ratio of the width of the feed port to the height of the feed port, nor the ratio of the length of the exit port to the diameter of the exit port, nor the ratio of the length of the spin chamber to the diameter of the exit port, nor the ratio of the exit port length to the exit port diameter, nor the diameter of the spray tip assembly, nor the diameter of the spray tip.

However, Duronio et al. discloses that varying the dimensions of the device may be made without deviating from the scope of the invention, see for example, column 4, lines 14-17, and column 5, lines 3-9, and lines 26-28 and lines 47-64, where Duronio discloses that having dimensions in certain ratios is preferable. It would have been obvious to provide a device as taught by Duronio et al. in the specific dimensions or ratios as claimed by Applicant, since such dimensions or ratios would not depart from the scope of the invention as taught by Duronio et al.

2. Claim 17 is rejected under 35 U.S.C. 103(a) as being unpatentable over Duronio et al., 6,328,229, in view of Sawhney et al., 6,121,341.

Duronio et al. disclose the invention substantially as claimed, except for the additional conduit being an optical fiber.

Sawhney et al. discloses a device for dispensing a fluid to a tissue surface with two chambers for receiving fluids, and an optical fiber (106) to deliver light from a

Art Unit: 1641

remote source for illumination during use of the device, see column 2, line 64 – column 3, line 7, and column 13, lines 37-56. It would have been obvious to combine Sawhney et al. with Duronio et al. since both disclose a device having two chambers for receiving fluids, the device being used for dispensing a fluid to a tissue surface. Specifically, it would have been obvious to provide an optical fiber as taught by Sawhney et al. in the Duronio et al. device, as it would be desirable for illumination of the treated site, as taught by Sawhney et al.

3. Claims 5-8 and 15 would be allowable if rewritten or amended to overcome the rejection(s) under 35 U.S.C. 112, second paragraph, set forth in this Office action.

The following is a statement of reasons for the indication of allowable subject matter: the combination of elements including a device having a first and second mechanical breakup unit and at least two first feed conduits for delivering fluid in the first mechanical breakup unit and into a first exit port, and at least two second feed conduits for delivering fluid to the second mechanical breakup unit and into a second exit port, wherein the first and second exit ports extend through the external surface of the spray tip of the device, was not found in the prior art search.

Response to Arguments

Applicant's arguments filed June 4, 2003 have been fully considered but they are not persuasive. Applicant argues that Duronio fails to teach or suggest first and second

Art Unit: 1641

exit ports extending through the external surface of the spray tip, enabling the materials dispensed from the fluid delivery device to be mixed external of the device, but rather the Duronio device mixes within the applicator prior to dispensing the material from the spray tip, see Applicant's response pages 13-14. Examiner reasserts that Figure 5 clearly shows that the exit ports extend through the external surface of the spray tip (at 46). Moreover, the device allows mixing of material external of the device, i.e., at external of orifice (48), (see Figure 5). In any case, Applicant has not even claimed this intended use.

As to claims 12 and 13, which were previously indicated as allowable, upon further consideration, Examiner believes that the above rejections are proper, and apologizes for any inconvenience.

Claims 12 and 13 do not positively recite structural limitations of the spin chamber which would distinguish the claims over the prior art, and do not otherwise distinguish over the prior art. That is, Duronio discloses a chamber and such chamber is capable of allowing fluid to spin. A recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In a claim drawn to a process of making, the intended use must result in a manipulative difference as compared to the prior art. See *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963).

Art Unit: 1641

Moreover, as to claims 12 and 13, as indicated in the above rejection, the device is capable of having a resulting spray cone of one of the fluids having a width greater than a resulting spray cone of the other fluid. (The spray cone of the fluids have different widths depending on the viscosity of the fluid and the velocity of the fluid being ejected.)


Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ann Y. Lam whose telephone number is (703) 306-5560. The examiner can normally be reached on M-Sat 11-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long V. Le can be reached on (703)305-3399. The fax phone numbers for the organization where this application or proceeding is assigned are (703)308-4242 for regular communications and (703)308-4426 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703)308-0196.


A.L.
August 19, 2003


LONG V. LE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600
08/25/03